

526 Rec'd/PCT/PTO 17 JUL 2001

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE  
REQUEST FOR FILING NATIONAL PHASE OF  
PCT APPLICATION UNDER 35 U.S.C. 371 AND 37 CFR 1.494 OR 1.495

09/889414



00909

To: Hon. Commissioner of Patents  
Washington, D.C. 20231

TRANSMITTAL LETTER TO THE UNITED STATES  
DESIGNATED/ELECTED OFFICE (DO/EO/US)

From: Pillsbury Winthrop LLP, IP Group:

Atty Dkt: P 0281558 IZ 70475/UST

M# /Client Ref.

Date: July 17, 2001

This is a REQUEST for FILING a PCT/USA National Phase Application based on:

International Application

PCT/GB00/00278

↑ country code

2. International Filing Date

1 February 2000

Day

MONTH

Year

3. Earliest Priority Date Claimed

6 February 1999

Day

MONTH

Year

(use item 2 if no earlier priority)

Measured from the earliest priority date in item 3, this PCT/USA National Phase Application Request is being filed within:

(a)  20 months from above item 3 date

(b)  30 months from above item 3 date,

(c) Therefore, the due date (unextendable) is August 6, 2001

Title of Invention DRUG COMBINATIONS COMPRISING (E)-7-[4-(4-FLUOROPHENYL)-6-ISOPROPYL-2-[METHYLSULFONYL] AMINO] PYRIMIDIN-5-YL] (3R,5S)-3,5-DIHYDROXYHEPT-6-ENOIC ACID AND AN INHIBITOR, INDUCER OR SUBSTRATE OF P450ISOENZYME 3A4

Inventor(s) RAZA, Ali et al

Applicant herewith submits the following under 35 U.S.C. 371 to effect filing:

Please immediately start national examination procedures (35 U.S.C. 371 (f)).

A copy of the International Application as filed (35 U.S.C. 371(c)(2)) is transmitted herewith (file if in English but, if in foreign language, file only if not transmitted to PTO by the International Bureau) including:

- a.  Request;
- b.  Abstract;
- c. 45 pgs. Spec. and Claims;
- d. \_\_\_\_\_ sheet(s) Drawing which are  informal  formal of size  A4  11"

A copy of the International Application has been transmitted by the International Bureau.

10. A translation of the International Application into English (35 U.S.C. 371(c)(2))  
a.  is transmitted herewith including: (1)  Request; (2)  Abstract;

(3) \_\_\_\_\_ pgs. Spec. and Claims;  
(4) \_\_\_\_\_ sheet(s) Drawing which are:

informal  formal of size  A4  11"

b.  is not required, as the application was filed in English.

c.  is not herewith, but will be filed when required by the forthcoming PTO Missing Requirements Notice per Rule 494(c) if box 4(a) is X'd or Rule 495(c) if box 4(b) is X'd.

d.  Translation verification attached (not required now).

PAT-112CN 4/01

9/889414

11.  Please see the attached Preliminary Amendment.
12.  Amendments to the claims of the International Application under PCT Article 19 (35 U.S.C. 371(c)(3)), i.e., before 18th month from first priority date above in item 3, are transmitted herewith (file only if in English) including:
13.  PCT Article 19 claim amendments (if any) have been transmitted by the International Bureau
14.  Translation of the amendments to the claims under PCT Article 19 (35 U.S.C. 371(c)(3)), i.e., of claim amendments made before 18th month, is attached (required by 20th month from the date in item 3 if box 4(a) above is X'd, or 30th month if box 4(b) is X'd, or else amendments will be considered canceled).
15. **A declaration of the inventor (35 U.S.C. 371(c)(4))**  
 a.  is submitted herewith       Original       Facsimile/Copy  
 b.  is not herewith, but will be filed when required by the forthcoming PTO Missing Requirements Notice per Rule 494(c) if box 4(a) is X'd or Rule 495(c) if box 4(b) is X'd.
16. **An International Search Report (ISR):**  
 a. Was prepared by  European Patent Office       Japanese Patent Office       Other  
 b.  has been transmitted by the international Bureau to PTO.  
 c.  copy herewith (1 pg(s).)       plus Annex of family members (1 pg(s).).
17. **International Preliminary Examination Report (IPER):**  
 a.  has been transmitted (if this letter is filed after 28 months from date in item 3) in English by the International Bureau with Annexes (if any) in original language.  
 b.  copy herewith in English.  
 c. 1  IPER Annex(es) in original language ("Annexes" are amendments made to claims/spec/drawings during Examination) including attached amended:  
 c. 2  Specification/claim pages # \_\_\_\_\_ claims # \_\_\_\_\_  
 Dwg Sheets # \_\_\_\_\_  
 d.  Translation of Annex(es) to IPER (required by 30<sup>th</sup> month due date, or else annexed amendments will be considered canceled).
18. **Information Disclosure Statement** including:  
 a.  Attached Form PTO-1449 listing documents  
 b.  Attached copies of documents listed on Form PTO-1449  
 c.  A concise explanation of relevance of ISR references is given in the ISR.
19.  **Assignment** document and Cover Sheet for recording are attached. Please mail the recorded assignment document back to the person whose signature, name and address appear at the end of this letter.
20.  Copy of Power to IA agent.
21.  **Drawings** (complete only if 8d or 10a(4) not completed): \_\_\_\_\_ sheet(s) per set:  1 set informal;  
 Formal of size  A4  11"
22. Small Entity Status  is Not claimed  is claimed (pre-filing confirmation required)  
 22(a) \_\_\_\_\_ (No.) Small Entity Statement(s) enclosed (since 9/8/00 Small Entity Statements(s) not essential to make claim)
23. Priority is hereby claimed under 35 U.S.C. 119/365 based on the priority claim and the certified copy, both filed in the International Application during the international stage based on the filing in (country) **GREAT BRITAIN** of:
- | Application No. | Filing Date      | Application No. | Filing Date   |
|-----------------|------------------|-----------------|---------------|
| (1) 9902593.4   | February 6, 1999 | (2) 9921063.5   | Sept. 8, 1999 |
| (3) 9921064.3   | Sept. 8, 1999    | (4) _____       | _____         |
| (5) _____       | _____            | (6) _____       | _____         |
- a.  See Form PCT/IB/304 sent to US/DO with copy of priority documents. If copy has not been received, please proceed promptly to obtain same from the IB.  
 b.  Copy of Form PCT/IB/304 attached.

JC17 Rec'd PCT/PTO 17 JUL 2001  
09889414

Page 3 of 4

RE: USA National Phase Filing of GB00/00278

24. Attached: 2 copies of Form PCT/IB/306

25. Per Item 17.c2, cancel original pages # \_\_\_\_\_, claims # \_\_\_\_\_, Drawing Sheets # \_\_\_\_\_

26. Calculation of the U.S. National Fee (35 U.S.C. 371 (c)(1)) and other fees is as follows:  
Based on amended claim(s) per above item(s)  12,  14,  17,  25 (hilite)

Total Effective Claims

Independent Claims

If any proper (ignore improper) Multiple Dependent claim is present,

minus 20 =  $x \$18/\$9 = \$0$

minus 3 =  $x \$80/\$40 = \$0$

add\$270/\$135 +0  $= \$0$

966/967

964/965

968/969

BASIC NATIONAL FEE (37 CFR 1.492(a)(1)-(4)): → BASIC FEE REQUIRED, NOW →→→  
↓

A. If country code letters in item 1 are not "US", "BR", "BB", "TT", "MX", "IL", "NZ", "IN" or "ZA"  
↓

See item 16 re:

1. Search Report was not prepared by EPO or JPO add\$1000/\$500
2. Search Report was prepared by EPO or JPO add\$860/\$430 +860

960/961

970/971

SKIP B, C, D AND E UNLESS country code letters in item 1 are "US", "BR", "BB", "TT", "MX", "IL", "NZ", "IN" or "ZA"  
↓

- B. If USPTO did not issue both International Search Report (ISR) and (if box 4(b) above is X'd) the International Examination Report (IPER), add\$1000/\$500 +0 960/961
- C. If USPTO issued ISR but not IPER (or box 4(a) above is X'd), add\$710/\$355 +0 958/959
- D. If USPTO issued IPER but IPER Sec. V boxes not all 3 YES, add\$690/\$345 +0 956/957
- E. If international preliminary examination fee was paid to USPTO and Rules 492(a)(4) and 496(b) satisfied (IPER Sec. V all 3 boxes YES for all claims), add \$100/\$50 +0 962/963

SUBTOTAL = \$860

27.

If Assignment box 19 above is X'd, add Assignment Recording fee of ---\$40

TOTAL FEES \$860

(581)

28.

If Assignment box 19 above is X'd, add Assignment Recording fee of ---\$40

  
00909

29.

Attached is a check to cover the - - -

Attestation

Attestation